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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IBSA INSTITUT BIOCHIMIQUE SA, IBSA PHARMA INC., and ALTERGON SA, Plaintiffs, v. ACCORD HEALTHCARE, INC., Defendant.	Civil Action No. 2:23-CV-00054-JXN-JBC

DEFENDANT'S OPENING CLAIM CONSTRUCTION BRIEF

Pursuant to Local Patent Rule 4.5 and the Court's Scheduling Order (Doc. No. 48), Defendant Accord Healthcare Inc. ("Accord") hereby submits its Opening *Markman* Brief.

I. INTRODUCTION

This is a patent infringement case concerning U.S. Patent Nos. 10,537,538 ("the '538 patent"), 11,096,913 ("the '913 patent") and 11,241,382 ("the 382 patent") (collectively the "Patents-in-Suit"). The Parties dispute the meaning of seven claim terms from the 382 patent. Accord contends that three of the terms are indefinite. The parties have agreed to defer issues of indefiniteness, as per the practice in this District. *See, e.g.*, Doc. No. 31.

With reference to the remaining four terms, first, the term "a temporal distance of less than 30 minutes from the closest meal consumed by the patient[,]" recited in claim 1, should be construed to mean "within 30 minutes after the patient's last meal." Plaintiffs' attempt to broaden the ordinary meaning of the term to mean "a time of less than 30 minutes before or after the closest meal consumed by the patient" is an improper attempt to rewrite the claims.

Second, the term "dosage unit" should be construed to mean a "single dose" and the term "the form of a dosage unit" should be construed to mean a "single dose container." Plaintiffs agree that the construction of these terms should include "a single dose." But, Plaintiffs' construction then also adds the language "or a part of a dose." There is no support for this additional language Plaintiffs seek to add to the construction.

Finally, the term "single dose container" should be construed to mean the embodiment disclosed at column 5, lines 41-51 of the 382 patent. An analysis of that specification as directed by Federal Circuit precedent reveals that the claim term "single dose container" must be read as limited to the specific embodiment disclosed in the specification.

II. LEGAL STANDARD

Courts "look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576,

1582 (Fed. Cir. 1996). There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution. *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)

Applying the above principles, Accord submits that its proposed constructions are correct and, respectfully, should be adopted.

III. ANALYSIS OF CLAIM TERMS IN DISPUTE

A. "a temporal distance of less than 30 minutes from the closest meal consumed by the patient"

Term	Patents/Claims	Accord's Proposal	Plaintiffs' Proposal
"a temporal distance of less than 30 minutes from the closest meal consumed by the patient"	382 patent, Cl. 1	Within 30 minutes after the patient's last meal	Plain and ordinary meaning, which is "a time of less than 30 minutes before or after the closest meal consumed by the patient"

Claim 1 recites:

> A method of treating a disease associated with deficiency of one or more thyroid hormones in a patient in need thereof, comprising:
>
> administering an effective amount of an oral solution pharmaceutical composition comprising T4 thyroid hormone in an alcohol-free, water-glycerol solution,
>
> wherein said composition is administered within *a temporal distance of less than 30 minutes from the closest meal consumed by the patient*.

Ex. A, 6:59-67. The parties appear to agree that "a temporal distance of less than 30 minutes" means "within 30 minutes" of the "closest meal consumed by the patient."

Thus, the crux of the dispute is centered around the meaning of the phrase "from the closest meal consumed by the patient" in the context of the claim limitation. Accord contends that the phrase means "after" the patient's last meal. Plaintiffs propose that phrase be construed to mean "before or after the closest meal consumed by the patient." In essence, Plaintiffs ask the Court to construe "from" to mean "before or after." Such a meaning is at odds with the plain meaning of the claim term.

1. Accord's Construction is the Correct Construction

a. The plain meaning of "less than 30 minutes *from* the closest meal consumed" is "30 minutes *after* the patient's last meal

"In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005)*. The word "from" as used in the disputed term is such a word. In the disputed term, "from" is used to indicate performing an action, *i.e.*, administration of composition, with reference to "a starting point." Ex. B; *see also PrinterOn Inc. v. BreezyPrint Corp.*, 93 F. Supp. 3d 658, 683 (S.D. Tex. 2015) (holding that "the ordinary meaning of "from" . . . mean[s] starting at a beginning point."). The action could be performed at a time before the reference beginning point or after the reference beginning point. The reference point in this case is "the closest meal consumed by the patient." The "30 minutes" is measured with reference to this point. In view of that definition, the wherein clause "said composition is administered within . . . 30 minutes from the closest meal consumed by the patient" means that the composition is administered within 30 minutes "from" that beginning point, *i.e.*, the closest meal consumed.

To determine if the composition is administered before or after that beginning point, *i.e.*, the closest meal consumed, a person of ordinary skill in the art would have looked at the surrounding words. *See Brookhill-Wilk 1, LLC. v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1299 (Fed. Cir. 2003) ("While certain terms may be at the center of the claim construction debate, the context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those terms."). As explained below, "the surrounding claim language provides context to the meaning of "from" that accords with [Accord's] arguments." *SimpleAir, Inc. v. Google, Inc.*, 2015 WL 1906016, at *7 (E.D. Tex. Apr. 27, 2015).

Specifically, the claim term includes the phrase "closest meal consumed." "Consumed" is the past tense of the verb "consume." The use of the past tense "consumed" means that the patient has eaten, *i.e.*, consumed, the meal and the composition is to be administered within 30 minutes of that meal having been "consumed," *i.e.*, after that meal, and the "closest meal" is necessarily the last meal. Accordingly, the ordinary meaning of "a temporal distance of less than 30 minutes from the closest meal consumed by the patient" is "[w]ithin 30 minutes after the patient's last meal." The claims do not, as Plaintiffs attempt to read them, recite "a temporal distance of less than 30 minutes from consum*ing* a meal."

b. The specification supports Accord's construction

If the claim language is clear on its face, as is the case here, then consideration of the other intrinsic evidence is limited "to determining if a deviation from the clear language of the claims is specified." *Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed.Cir.2001); *see also Brookhill-Wilk 1*, 334 F.3d at 1298 ("The written description must be examined in every case, because it is relevant not only to aid in the claim construction analysis, but also to determine if the presumption of ordinary and customary meaning is rebutted."). The intrinsic evidence neither

rebuts the presumption that the ordinary meaning of "from," as described above, applies nor requires a deviation from the clear language of the claims. To the contrary, the specification confirms that Accord's construction is the correct construction because the specification uses different language than "from" when discussing administrations before a meal and distinguishes between administration *before* a meal and administration within a timeframe *from* a meal. Specifically, when describing administering the formulation after a meal, the inventors used the preposition "from" to indicate that the starting point was the consumption of the meal and that the composition was administered from that starting point, i.e., after the meal. *See e.g.*, Ex. A, 2:29 ("oral formulations of T4 are recommended in therapy for administration before meals and distant *from* them[, *i.e.*, meals]") (emphasis added).

Similarly, the specification distinguishes between the use of the past tense "consume*d*" and future tense "will consume." Ex. A at 4:5-7 ("said patients being selected among those who have consumed (or will consume) the closest meal"). The inventors thus knew how to recite administration before a user "will consume" a meal and administration at a time "from" which the meal was "consumed" and opted to claim only the latter.

2. Plaintiffs' Construction Should be Rejected

Plaintiffs' proposed construction is wrong; however, it is not surprising because that is the only construction that can support a finding of infringement and yet not run afoul of the various cannons of claim construction.[1] Although, "the function of the Court in 'construing' claims is not to 'rewrite' the claims," what Plaintiffs seek is just that. *Diversey, Inc. v. POPS Techs. LLC,* 2021

[1] It is also not clear (i) if there is 35 U.S.C. §112 support for Plaintiffs' proposed construction and (ii) how such a claim can pass muster under 35 U.S.C §101. Those validity concerns will be implicated if Plaintiffs' construction is adopted.

WL 3396803, at *21 (N.D. Ga. June 14, 2021), report and recommendation adopted, 2022 WL 886220 (N.D. Ga. Jan. 12, 2022). The Court should decline Plaintiffs' request and give "effect to the terms chosen by the patentee." *Acceleration Bay LLC v. Activision Blizzard, Inc.*, 324 F. Supp. 3d 470, 478 (D. Del. 2018) (*citing K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999)).

The plain meaning of "from" as informed by the phrase "closest meal *consumed*" cannot mean "before or after."

Although "claim terms must be construed in light of the specification and prosecution history, and cannot be considered in isolation[,]" "the specification and prosecution history only compel departure from the plain meaning in two instances: lexicography and disavowal." *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1308–09 (Fed. Cir. 2014). "The standards for finding lexicography and disavowal are exacting. To act as its own lexicographer, a patentee must 'clearly set forth a definition of the disputed claim term,' and 'clearly express an intent to define the term.'" *Id.* (*quoting SciMed Life Sys. Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001) and *citing Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)). Here there is neither lexicography nor disavowal that would compel departure from the plain meaning of "from the closest meal consumed."

To the contrary, as explained above, the specification supports Accord's construction, and at the least does not *clearly* redefine "from" a meal "consumed" to mean "before or after" a meal. "[T]o be his own lexicographer, a patentee must *use a special definition of the term that is clearly stated in the patent specification or file history*." *Laryngeal Mask Co. Ltd. v. Ambu*, 618 F.3d 1367, 1372 (Fed. Cir. 2010) (emphasis added). The inventors here did not.

B. "dosage unit"

Term	Patents/Claims	Accord's Proposal	Plaintiffs' Proposal
"dosage unit"	382 patent, Cls. 7, 8, 15, and 16	"single dose"	Plain and ordinary meaning, which is "unit of a pharmaceutical composition that contains a single dose or part of a dose"

1. Accord's Construction is the Correct Construction

Although there is limited discussion in the 382 patent regarding the term "dosage unit," the 382 patent specification makes clear that the specific dose to be administered is critical and is to be administered as a single dose or "unit." "Dose accuracy" is critical and claims 7-8 and 15-16 direct that the method of administering must be in "the form of a dosage unit." Accord submits that the language of the specification in combination with the reference in the claims supports that the dosage unit must be a single dose to be administered to the patient. Plaintiffs themselves agree that the construction properly encompasses the term "single dose." As detailed below, however, Plaintiffs' further proposed inclusion of the phrase "or part of a dose" is simply not supported anywhere in the intrinsic evidence.

The 382 patent emphasizes that the "correct dose" is critical:

> **The selection of the correct dose is a critical aspect of thyroid hormonal treatments**: under dosing results in low response, while an excessive dose can cause toxic hyperthyroidism symptoms such as tachycardia, sweating, weight loss, nervousness, diarrhea, bone resorption due to activation of osteoclasts and cardiac problems. It is therefore important for patients to rely on formulations which are **reliable in terms of dose accuracy**. A quantitative absorption of the administered dose is particularly desired and is important in the case of T4 hormone…

382 patent, 2:4-14.

The 382 patent specification uses the term "dosage unit" only once, equating "single dosage units" with a "single-dose package" and ties the "suitable dose unit" to a specific amount of T4 hormone, which as noted above is the critical aspect of the treatment:

> Preferably, the present water-glycerol solutions are formulated and packaged as **single dosage units (single-dose package)**; in this case, the **suitable dose unit** will typically contain from 5 to 1000 μg (or preferably from 10 to 500 μg) of T4 hormone.

382 patent, 4:28-32.

Thus, even though the guidance in the specification is limited, the combination of the teaching that (i) the correct dose is critical and (ii) the dose must be administered in a single dosage unit in a method for treating a patient, supports that the term "dosage unit" should be construed to mean "single unit."

2. Plaintiffs' Litigation-inspired Construction should be Rejected

Plaintiffs' proposed construction of "a single dose or part of a dose" finds no support in the specification or the prior art reference (WO2018/073209) (Exhibit C) relied on by Plaintiffs as supporting evidence. The portions of that prior art reference cited by Plaintiffs describe the form of the dosage unit as a very specific type of packaging designed to prevent the disintegration of the T4 hormone. See Exhibit C at 3:11-16 ("packaged via container arrangements suitable to maintain a general stability of the solution."); 3:24-4:30 ("The packaging used in the present invention is a multi-barrier one…"); 7:24-8:13 ("single-dose container").

There is no intrinsic evidence that supports Plaintiffs' construction of "or part of a dose."

For all of the above reasons, the Court should adopt Accord's construction.

C. "the form of a dosage unit"

Term	Patents/Claims	Defendants' Proposal	Plaintiffs' Proposal

"the form of a dosage unit"	382 patent, Cls. 7, 8, 15, and 16	Single dose container	Plain and ordinary meaning, which is "the form of a unit of a pharmaceutical composition that contains a single dose or part of a dose"

1. Accord's Construction is the Correct Construction

For this term as well, the specification provides little guidance. The specification identifies that the formulations disclosed can be provided in "conveniently packaged form." Thus, the 382 patent conveys that the form of the dosage unit is the packaging in which the formulation is packaged. The specification references (i) the "form is an oral tablet" (2:51) and (ii) "above-mentioned forms" referring to solutions (4:9), but neither of those uses of the term "forms" is instructive.

The term "form" cannot be understood to reference whether the dosage unit is a tablet or solution because claim 7 defines that the subject of the claim is a *solution*: "method of claim 3, wherein said water-glycerol solution is in the form of a dosage unit."

Thus, the term "form" must be referencing the packaging for the dosage unit, and the ***only type*** of packaging disclosed is a single dose container.

2. Plaintiffs' Construction should be Rejected

Plaintiffs provide no guidance as to what the term "form" means. For all of the above reasons, the Court should adopt Accord's construction.

D. "single dose container"

Term	Patents/Claims	Defendants' Proposal	Plaintiffs' Proposal
"single dose container"	382 patent, Cl. 20	multicomponent laminated containers made of layers of	Plain and ordinary meaning, which is "container

		polyethylene, ethylene vinyl alcohol copolymer resins, polyvinyl chloride, polyvinylidene chloride, polyvinyl acetate, fluorinated-chlorinated resins, ionomer resins, cyclic olefin copolymers, polyamide, polystyrene, polycarbonate, laminated metals, paper, obtaining containers with an ideal squeezing degree, so as to ensure complete discharge of the dose of solution by manual compression of the container, associated with an excellent protection of the solution	that holds a single dose"

1. Accord's Construction is the Correct Construction

The 382 patent incorporates by reference WO2018/073209 (Exhibit C). 382 patent, 4:41-45. That reference is entitled "High-Stability Packaged Solutions of T4 Thyroid Hormone" and discloses the instability of T4 hormone formulations that are the subject of the 382 patent and packaging for those formulations. WO2018/073209 discloses a need for specific packaging to preserve the stability of the T4 hormone formulations:

> It was now unexpectedly found that the unwanted premature conversion of T4 to T3 in packaged solution can be significantly reduced if T4 is formulated in water glycerol, alcohol-free solutions. The invention thus relates to highly stable alcohol free water-glycerol solutions of T4 thyroid hormone, with a reduced amount of T3 impurity, **ready-to-use packaged via container arrangements suitable to maintain a general stability of the solution**. The container are multi-barrier ones,

> in which several layers of different materials separate the solution from contact with the external environment.

WO2018/073209 (Exhibit C) at 3:9-16 (emphasis added).

The 382 patent describes the "single dose container" that can provide the stability necessary for a T4 hormone formulation in a very specific configuration – a squeezable single-dose container made of very specific components:

> An advantageous mode of packaging is represented by **squeezable single-dose containers**; in particular, as described in WO2018/073209, multicomponent laminated containers made of layers of polyethylene, ethylene vinyl alcohol copolymer resins, polyvinyl chloride, polyvinylidene chloride, polyvinyl acetate, fluorinated-chlorinated resins, ionomer resins, cyclic olefin copolymers, polyamide, polystyrene, polycarbonate, laminated metals, paper, obtaining containers with an ideal squeezing degree, so as to ensure complete discharge of the dose of solution by manual compression of the container, **associated with an excellent protection of the solution**…

382 patent (Exhibit A), 5:41-51 (emphasis added).

The above passage of the 382 patent notes that it is this "particular" packaging that sustains the stability of the formulation that is the subject of the 382 patent.

"Claims must be read in view of the specification, of which they are a part." *Markman v. Westview Instruments*, 52 F.3d 967, 979-980 (Fed.Cir.1995). "One purpose for examining the specification is to determine if the patentee has limited the scope of the claims." *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882 (Fed.Cir.2000). "Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001). *See also Wang Labs., Inc. v. America Online, Inc.*, 197 F.3d 1377, 1382 (Fed.Cir.1999) (construing claims as limited to

one of two disclosed character-based systems because the "only system that is described and enabled" in the patent specification "uses a character-based protocol").

In *Forest Lab'ys, LLC v. Sigmapharm Lab'ys, LLC*, the Federal circuit noted that even though independent claim 1 "does not expressly refer to buccal or sublingual administration," the claims must be read as so limited because "[when] a patent ... describes the features of the 'present invention' as a whole, this description limits the scope of the invention." *Forest Lab'ys, LLC v. Sigmapharm Lab'ys, LLC*, 918 F.3d 928, 933 (Fed. Cir. 2019), quoting *Verizon Servs. Corp. v. Vonage Holdings Corp*., 503 F.3d 1295, 1308 (Fed. Cir. 2007).

The *Forest Lab'ys* court also noted that the construction is further supported by "additional language in the specification, which explains the benefits of sublingual and buccal treatment over the prior art" as well as the title of the patent, "Sublingual or Buccal Pharmaceutical Composition." *Forest Lab'ys,* 503 F.3d at 933. Here, as noted above, the 382 patent incorporates by reference WO2018/073209. WO2018/073209 details the specific packaging requirements to maintain stability of the T4 hormone treatment. (Exhibit C at 3:24-4:6). Also, as noted above, that reference is entitled "High-Stability Packaged Solutions of T4 Thyroid Hormone," indicating that it is directed to a limited type of packaging.

The 382 patent adopts one specific packaging arrangement disclosed in WO2018/073209 as the "particular" type of "single dose container" for use with the T4 hormone treatment formulations that are the subject of the 382 patent. In view of the details provided by the 382 patent specification, Accord submits that the term "single dose container" should be construed to mean the embodiment disclosed at column 5, lines 41-51 of the 382 patent.

2. Plaintiffs' Construction should be Rejected

Although Plaintiffs agree that WO2018/073209 is incorporated by reference into the 382 patent (Doc. No. 68, page ID 379, n. 2) and cite to a number of passages from that reference as relevant to construction of this claim term (Id. at page ID 382), Plaintiffs do not provide a critical analysis of how the claim term "single dose container" should be read in view of the specification of the 382 patent, which includes the disclosure WO2018/073209. An analysis of that specification as directed by Federal Circuit precedent reveals that the claim term "single dose container" must be read as limited to the specific embodiment disclosed at column 5, lines 41-51 of the 382 patent.

For all of the above reasons, the Court should adopt Accord's construction.

CONCLUSION

For the foregoing reasons, Accord respectfully requests that the Court adopt Accord's proposed construction for the disputed terms.

Respectfully submitted,

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